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| APPLICATION NO.                   | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|---------------|----------------------|---------------------|------------------|
| 10/580,727                        | 07/03/2007    | Henrik Stender       | 60218(48497)        | 6468             |
| 21874                             | 7590          | 06/08/2010           | EXAMINER            |                  |
| EDWARDS ANGELL PALMER & DODGE LLP |               |                      | DUFFY, PATRICIA ANN |                  |
| P.O. BOX 55874                    |               |                      | ART UNIT            | PAPER NUMBER     |
| BOSTON, MA 02205                  |               |                      | 1645                |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/580,727             | STENDER ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Patricia A. Duffy      | 1645                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 3-8-2010.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 3-13,25,26,30 and 51-62 is/are pending in the application.  
 4a) Of the above claim(s) 51-61 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 3-13,25,26,30 and 62 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____ .                        |

#### **RESPONSE TO AMENDMENT**

The amendment filed 3-8-01 has been entered into the record. Claims 1, 2, 14-24, 27-29 and 31-50 have been cancelled. Claims 3-13, 25, 26, 30 and 51-62 are pending. Claims 3-13, 25, 26, 30 and 62 are under examination. Claims 51-61 are withdrawn from consideration.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

#### ***Rejections Withdrawn***

The rejection of claims 3-13, 25, 26 and 30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn based on Applicants amendments to the claims.

The rejection of claims 3-13, 25, 26 and 30 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn based on Applicants amendments to the claims.

Claim 3-13, 25, 26, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in part.

As to claim 25 and all dependent claims, it is unclear from the claim construction how many probes must be present in the probe set, at least three - is withdrawn based on Applicants amendment to the claims.

As to claim 3, the term "the *Staphylococcus* probe" is indefinite inasmuch as it lacks antecedent basis in the independent claim 25 - is withdrawn based on Applicants amendment to the claims.

As to claims 3-13, the claims are *prima facie* indefinite as the term "the PNA probe of claim 25", lacks clear and unambiguous support in the independent claim 25 from which they depend. Claim 25 is directed to a PNA probe set and not a probe *per se* and as such,

it is unclear to which of the probes in the probe set, the dependent claims reference. These are both withdrawn based on the amendment to the claims.

#### *Rejections Maintained*

Claim 3-13, 25, 26, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 3-13, the claims are also confusing in that the claims recite "a target sequence" and the specification teaches that the target sequence is a nucleobase sequence and the claims do not recite a nucleobase sequence.

Applicant's arguments have been carefully considered but are not persuasive. Applicants argue the definition of a probe and how they are designed to bind to a target sequence. This is the issue because the target sequence is not recited in the claims. The claims do not set forth the sequence of the target sequence and therefore the metes and bounds of the probe cannot be ascertained since no target sequence is set forth in the claims or in the specification as filed.

#### *New Rejections Based on Amendment*

Claims 3-13, 25, 26 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims as amended now recite that the PNA probes are at least 95% homologous to SEQ ID NOs:6, 7 or 8. Applicants point to pages 15-16 and Example 5 for support of these new limitations. The specification teaches at pages 15-16 (bridging paragraph) that "Consequently, the probing nucleobase sequence may be only as much as

86% homologous to the probing nucleobase sequences identified above." The concept of variation of "at least 95%" does not have written description in the specification as filed as only a single point is described and "only as much as 86% homologous" identifies only a lower limit and that specific passage does not convey the range above 86%.. nor specifically defines the end point of 95% homologous. That is the specification at pages 15-16, does not support the now claimed range. Applicants also point to Example 5 on page 29 for support. The example uses the particular probes of SEQ ID NOS:6, 7 and 8. However, no descriptive support for the newly claimed range of "at least 95% homologous" to any of the particular sequences can be found in Example 5. Given the lack of particulars with respect to conception by way of written description for this later claimed subject material, the skilled artisan would not have recognized that Applicants had possession of the later claimed invention as claimed by percent homology to each of the recited sequences at the time of filing. Applicants have not described the genus of probes 95% homologous to any of SEQ ID NOS:6, 7, or 8.

Claims 3-13, 25, 26 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims recite a probe set "at least 95% homologous to" SEQ ID NO:6, SEQ ID NO:7 and SEQ ID NO:8. Dependent claims recite probes suitable for analysis of *S. epidermidis*, *S. hominis*, *S. haemolyticus*, *S. lugdunesis*, *S. saprophyticus*. The specification teaches:

TCT-AAC-ATG-TTC-TIT (Seq. Id. No. 1) targeting *Staphylococcus epidermidis*,

TCT-AGT-CTG-TTC-TTT (Seq. Id. No. 2) targeting *Staphylococcus saprophyticus*,

TCT-AAT-ATA-TTC-CTT (Seq. Id. No. 3) targeting *Staphylococcus haemolyticus*,  
TCT-AAT-ATA-TAC-TTT (Seq. Id. No. 4) targeting *Staphylococcus warneri*,  
GCT-CCA-AAT-GGT-TAC (Seq. Id. No. 5) targeting several *Staphylococcus* species other  
than *Staphylococcus aureus*,  
TCC-TCG-TCT-GTT-CGC (Seq. Id. No. 6) targeting *Staphylococcus epidermidis*,  
CTC-CTT-ATC-TGT-TCG-C (Seq. Id. No. 7) targeting *Staphylococcus saprophyticus*,  
CTC-CTT-GTC-TGT-TCG-C (Seq. Id. No. 8) targeting *Staphylococcus haemolyticus*,  
CTT-CTC-ATC-TGT-TCG-C (Seq. Id. No. 9), targeting *Staphylococcus sciud*,  
TCC-TCG-TCC-GTT-CGC (Seq. Id. No. 10), targeting *Staphylococcus schleifed*, and TCC-  
TTG-TCC-GTT-CGC (Seq. Id. No. 11) targeting a variant of *Staphylococcus schleiferi*.  
(specification page 5). The specification also teaches the use of the probe set of SEQ ID  
NOS: 6, 7 and 8 (CNS3, CNS4 and CNS5 respectively) at Example 5, pages 28-29 of the  
specification.

The specification does not teach variants of SEQ IN NOS:6, 7 or 8. The  
specification does not teach the "target sequence" in genome or nucleobase sequence of  
the microorganism such that the skilled artisan would be able to readily envision other  
PNA probes for targeting. The specification teaches that they are directed to a  
"phylogenetically conserved region of rRNA target sequence that varies slightly between  
*Staphylococcus* species". However, the specification does not describe what rRNA  
sequence that is the target. It does not teach the nucleobase sequence(s) of the "rRNA"  
phylogenetically conserved sequence. The specification does not teach the "target  
sequences" or the nucleobase sequences from the phylogenetically conserved rRNA

sequences of the recited *Staphylococcus* species, such that one skilled in this art could readily envisage variants that are useful for detection.

The courts have held that when the specification discloses at most a specific DNA segment known to the inventor, the disclosure is not commensurate with the claims (*Ex parte Maizel*, 27 USPQ2d 1662). Other than identifying the specific probes of SEQ I NDOS: 6, 7 and 8, the specification does not teach those nucleobases within each that that can be inserted, substituted or deleted, to arrive at a variant that maintains functionally of the probe set as described in the specification as useful for detection of *Staphylococcus* spp. Although the disclosure would put the skilled artisan in possession of multiple different individual single substitutions, insertions or deletions that may or may not retain inducible activity, the level of skill and knowledge in the art is such that one of ordinary skill would not be able to identify without further testing, which of those nucleic acids that have the claimed activities because the specification does not disclose the target sequence. The specification lacks written description of the target nucleobase rRNA structures of the *Staphylococcus* species of the alleged phylogenetically conserved region. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.). As such, the skilled artisan would not readily appreciate from the comparison that Applicants were in possession of the now claimed invention. The courts have held that possession of a genus may not be shown by merely describing how to obtain members of the claimed genus (i.e. make and test to see if they lack the requisite activity) or how to identify their common structural features. See *University of Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895 and *Ex Parte Kubin et al.*

Appeal 2007-0819, May 31, 2007. In addition, the court has held that a method of identification of compounds (i.e. screening for variants) is not a description of the compounds *per se* that meet the requisite function to use in the associated methods. *University of Rochester v. G.D. Searle & Co.* 69 USPQ2D 1886 (CAFC 2004). Finally, function of a probe does not describe a structure, because the specification does not provide relevant identifying characteristics, including functional characteristics when coupled with known or disclosed correlation between function and structure. The courts have held that in these instances, the specification lacks written description see *Enzo Biochem Inc. v. Gen-Probe Inc.* 63 USPQ2D 1609 (CAFC 2002) and *University of Rochester v. G.D. Searle & Co.* 69 USPQ2D 1886 (CAFC 2004). When the genus is large and the specification lacks a known (art described) or disclosed correlation between structure and function, the written description of the specification does not convey possession of the claimed genus of 95% homologous variants of SEQ ID NOS:6, or 7 or 8 as claimed.

Applicants arguments with respect to the 86% identical rejection, the rationale of which is identical to that set forth above, have been considered but are not persuasive. Applicants argue that Guo et al teach that one skilled in the art could readily envisage variants useful for detection. This is not persuasive because as applicant and Guo et al explain, the skilled artisan would have to have knowledge of the probe and the target sequence (see response page 7, last paragraph). In the instant case, as explained above the specification does not teach the "target sequence" in genome or nucleobase sequence of the microorganism of the claims. Absent the description of the particular target sequence, the skilled artisan would be unable to design variants of SEQ ID NOS:6, 7 and 8 as probes falling within the claimed genus that are "suitable" for analysis as claimed. Applicants' have no written description for any of these other desirable compounds are not enabled for such and that applicants' are not entitled for dominance of further

patentable inventions by claims that are insufficiently supported by the specification (*In re Fisher*, 166 USPQ 18, CCPA (1970)).

*It is noted that the instant claims do not enjoy priority to the provisional document 60/525,591 filed 11-26-03. As such, the claims have been accorded the filing date of 11-24-04 for prior art purposes.*

Claims 3-13, 25, 26, 30 and new claim 62 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hashida et al (WO 03/106676 published 12-24-2003) in view of Ray et al (FASEB Journal, 14:1041-1060, 2000) for reasons made of record in the Office Action mailed 12-10-09.

Applicants arguments have been carefully considered but are not persuasive. Applicants argue that the probes all target sequences that are either genus or species specific and that the design of such probes to simultaneously detect and discriminate among a cohort of species. This is not persuasive because Applicants are arguing the intended use of the combination for discrimination when *limited to an admixture of SEQ ID NOS:6, 7 and 8*. Applicants arguments with respect to intended use of the probe set is not persuasive as the probe set as combined is useful for detection *per se*. Applicants argue that Hashida et al teach probes that are species specific. The species-specific nature of the probes is irrelevant as the claims are drawn to probe sets and not intended use of the probes for genus-species discrimination. Applicants argue that nowhere in Hashida et al teach to pick out probes having SEQ ID NOS: 6, 7, and 8 from the probe sets. This is not persuasive, it is obvious to combine the probes Hashida in a combined probe set for mere detection purposes and the instant probe set has open language and is not limited to a probe set consisting of the probes set forth in SEQ ID NOS:6, 7 and 8 and Hashida et al teach the use of probe combinations on chips (i.e. the instant probe set). The combination of probes and probe sets as set forth by Hashida et al alone for

detection or present as combinations on chips as modified by Ray et al as useful for detection of *Staphylococcus* species is *prima facie* obvious. The combination of probes in kits is further *prima facie* obvious because kits provide economy and convenience for the consumer.

*Status of Claims*

Claims 3-13, 25, 26, 30 and 62 stand rejected. Claims 51-61 are withdrawn from consideration.

*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisors, Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/  
Primary Examiner